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WHAT YOU NEED TO KNOW

about

CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION

Assessing the health risk of pesticides

THE MISSION of Cal/EPA's Department of Pesticide Regulation (DPR) is to ensure that people and the environment are protected from adverse (harmful) effects that may be associated with pesticide use. Determining what those impacts might be and under what circumstances they can occur is essential to an effective regulatory program. When this information is known, measures can be taken to limit exposures so that adverse effects can be avoided.

There are more than 865 active ingredients registered as pesticides, which are formulated into thousands of pesticide products available in the marketplace. About 350 pesticides are used on the foods we eat and to protect our homes and pets.

DPR scientifically evaluates the hazards of pesticides before they can be sold in California. Chemicals already in use are also subject to periodic reevaluation. Risk assessment plays a critical role in this process and is often the driving force behind new regulations and other use restrictions. DPR takes a multimedia approach to risk assessment and assesses potential dietary, workplace, residential, and ambient air exposures.

What is risk assessment?

Toxicity is an inherent property of all substances. All chemical substances can produce adverse health effects at some level of exposure. In this context, risk is the likelihood that an adverse health effect will result from an exposure (or exposures) to a particular amount (dose) of a chemical. Therefore, risk is a function of both toxicity and exposure. Risk assessment is a process designed to answer questions about how toxic a chemical is, what exposure results from its various uses, what is the probability that use will cause harm, and how to characterize that risk.

A 1997 evaluation of Cal/EPA risk assessment policies and practices said that although "risk assessment is known to have considerable uncertainty, and there are difficulties in applying this imperfect process to decision-making, ... (it) helps prevent arbitrary decisions by providing a systematic means of incorporating scientific information into decision-making." In this light, DPR conducts health risk assessments on pesticide active ingredients to find out if they are being used (or can be used under modified conditions) in a way that is safe for both users and the general population.

Risk assessment is a process designed to answer questions about how toxic a chemical is, what exposure results from its various uses, what is the probability that use will cause harm, and how to characterize that risk.

The 1997 review concluded that DPR's risk assessment practices are generally consistent with the systematic scientific framework used by the U.S. Environmental Protection Agency (U.S. EPA) and similar regulatory agencies. Where differences exist, they mostly arise from differences in law, or from situations where California differs significantly from the average for the U.S., such as in diet, climate, agricultural practices, or population demographics.

How are risk assessments conducted?

DPR, like U.S. EPA and other agencies, views risk assessment as consisting of four elements:

- Hazard identification
- Dose-response assessment
- Exposure assessment
- Risk characterization

Hazard identification involves the review and evaluation of a chemical's toxic properties - the extent and type of adverse health effects. Laboratory studies on animals are generally used to define the types of toxic effects caused by a chemical and the exposure levels (doses) at which these effects may be seen. In evaluating chemicals, scientists must determine the exposure level at which adverse effects would not be expected to occur.

Dose-response assessment considers the toxic properties of a chemical and determines the lowest dose of the chemical that results in an adverse effect. State and federal tests require that laboratory animals receive high enough doses to produce toxic effects. Animals receive a wide range of exposures, including doses that may be much higher than those to which people might be exposed. There also are doses at which no ill effects occur in the test animals. Within that range of doses, the highest tested dose that does not cause adverse effects is the "no observed effect level" (NOEL).

Uncertainty factors are mathematical adjustments used when scientists have some but not all information. One way they are used in risk assessments is to compensate for uncertainties in the process that estimates the dose level in humans at which there is reasonable certainty that the identified adverse effects will not occur. As a default, if the toxicity studies are based on animals, we generally use an uncertainty factor of 10 to account for assumed differences in sensitivity between humans and experimental animals to a chemical (an assumption that the least sensitive humans are 10 times more sensitive than the most sensitive animal species). An additional uncertainty factor of 10 is used to address differences in sensitivity among humans (this assumes that the most sensitive human is 10 times more sensitive than the least sensitive human). This results in a total uncertainty factor of 100.

Exposure assessment is the process of finding out how people come into contact with the pesticide, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with. It includes an estimate of people's potential exposure to a chemical at work, at home, or in their diets.

Exposure may be of short duration (acute, occurring once or for a short time), intermediate duration (subchronic, generally one to three months), or long-term (chronic, generally one year to lifetime). Rates of exposure are determined for breathing (inhalation), eating or drinking (ingestion), or contact with the skin (dermal absorption), depending on the chemical and the ways people may be exposed to it.

Risk characterization quantifies the results of the risk assessment. Risk characterization combines hazard identification and dose-response assessment (generally based on animal studies) with exposure assessment (based on estimated human exposure).

For example, characterizing the risk to pesticide applicators requires estimating what dose of the chemical causes what effects (that is, the dose-response assessment), and what dose workers are exposed to (the exposure assessment). The results are often expressed in one of two ways. The first is as a margin of exposure, which is calculated by dividing the NOEL by the estimated human exposure. If the NOEL is based on a study using experimental animals, the benchmark margin of exposure would be 100 to assure that there is reasonable certainty that the effect will not occur in exposed people.

For cancer effects, risk is often expressed another way, as how much more likely it is that cancer will result from exposure to a chemical. Often, this is simplified in a kind of scientific shorthand, for example, a cancer risk of "one in a million" in a given population. This can give the inaccurate impression that science can determine that exactly one person in a million will develop cancer, that we can determine and measure the causes of all cancers. The inherent uncertainty in risk assessment means that risk assessors can only predict the probability of risk.

How does DPR collect the information used to assess risk?

DPR evaluates and registers pesticides before they are sold or used in California. The statutory guidelines require companies who wish to sell pesticides in California to submit tests and studies to DPR for evaluation. DPR's requirements for this data are very similar to those of U.S. EPA, although DPR sometimes requires some additional specific data (for example, on worker exposure, or potential to contaminate ground water). Registrants may conduct the studies themselves or hire laboratories to do testing.

Pesticide registration data requirements provide scientists with an extensive repository of information from which to make evaluations and draw conclusions. (This is not required for any other class of industrial chemicals; only pharmaceuticals are this extensively studied before use is allowed.) DPR scientists also research the entire scientific literature to locate additional information on pesticides, to ensure that their conclusions are based on the most accurate, timely information on potential hazards to human health.

Do other scientists review DPR's risk assessments?

Yes, DPR's risk assessments are subject to rigorous peer review by objective, nongovernmental scientists with expertise in the scientific disciplines covered in the assessment. DPR presents the four components of the risk assessment in a risk characterization document (RCD). The RCDs also contain a risk appraisal section, which delineates the limitations, assumptions, and uncertainties in the risk assessment. The initial RCD draft undergoes internal departmental peer review by DPR scientists. After completing departmental review, the RCD currently undergoes peer review by scientists at the Office of Environmental Health Hazard Assessment (OEHHHA), another branch of Cal/EPA, and by scientists at U.S. EPA. DPR also uses other scientific experts for additional external peer review (e.g., scientists from the University of California). External peer review provides critical information for DPR on the scientific completeness of its documents. DPR reviews the comments, responds to the reviewers, and makes changes as appropriate. In addition, as new data become available, DPR may update the RCD with appendices.

How does DPR use the results of a risk assessment?

DPR management reviews the results of the risk assessment and determines if the calculated risks are unacceptable (that is, an inadequate margin of exposure or a significant cancer risk). If risks are unacceptable, DPR then determines if risks can be controlled or mitigated. This is part of the risk management process.

Risk managers use risk assessment as an important tool to determine the acceptability of a level of exposure and then reduce exposures to that level. Risk management, unlike risk assessment, is not based solely on scientific considerations, since it also involves social, economic, and legal considerations to make regulatory and policy decisions.

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What is risk management?

Risk management is the evaluation and selection of mitigation options. Risk managers use risk assessment as an important tool to determine the acceptability of a level of exposure and then reduce exposures to that level. Unlike risk assessment, risk management is not based solely on scientific considerations, since it also involves social, economic, and legal considerations to make regulatory and policy decisions. DPR considers these factors in analyzing the possible regulatory responses to potential health hazards. The process is necessarily subjective in that it requires value judgments on the acceptability of risks and the reasonableness of control measures. However, the bottom line is simple: DPR will not allow a chemical to be used unless it can be used safely.

The process of risk assessment is separate from risk management. Risk assessment often drives risk management, but risk management cannot and does not drive risk assessment at DPR. Risk assessments and risk management options are developed by separate DPR branches and are described in separate formal documents.

The National Academy of Sciences (NAS) seminal 1983 report, *Risk Assessment in the Federal Government: Managing the Process*, formed the foundation for the risk assessment process in general and for regulatory agencies in particular. In this report, the NAS specifically addressed the separation of risk assessment and risk management. Contrary to oft-repeated misinterpretations, the report did not recommend an organizational separation of risk assessment and risk management (that is, placing the two processes in separate organizations). Rather, the report recommended the maintenance of a "clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies."

What other departments conduct risk assessment and risk management activities?

DPR is not the only State agency that conducts both. The Department of Toxic Substances Control assesses exposure to various hazardous chemicals and manages the associated risks. The Department of Fish and Game assesses ecological toxicology and exposure of aquatic and terrestrial organisms to various chemicals, and jointly manages the associated risks with the State and Regional Water Boards; and the Department of Health Services determines human exposure to chemicals in drinking water and manages the associated risks. OEHHA conducts risk assessments and has a statutorily mandated "joint and mutual responsibility" with DPR for the development of regulations regarding pesticides and worker safety. The development of regulations relating to worker safety is a risk management activity.

What is the reputation of DPR's risk assessment activities?

DPR's current risk assessment activities are state of the art and widely recognized to be world-class and scientifically sound. DPR separates its risk management activities from its risk assessment function, so that risk management decisions are made transparently, using the recommendations from the risk assessors. Additionally, risk assessments are subjected to rigorous peer review by academic experts both within and outside of California.